UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN RESPONSE TO DEFENDANTS' REQUEST FOR A STATUS CONFERENCE

Plaintiffs do not oppose defendants' suggestion that a status conference would greatly assist the parties. There are at least two issues that create the need for judicial direction. First, as a result of delays in production by defendants and third parties, plaintiffs cannot complete fact discovery by the March 1, 2004 deadline. Plaintiffs believe that such discovery can be completed by May 1, 2004 and propose a sixty day extension of all deadlines for the first group of drugs subject to discovery. Second, plaintiffs agree that a status conference would clarify the drugs at issue pursuant to the November 21, 2003 order. Since the Court indicated that discovery should go forward on brand name Part B drugs, certain companies have flat out refused to respond despite acknowledging that they make drugs covered by the order and still others place limitations on what "Part B" means that are not justified by the allegations of the AMCC. Third, looking down the road, plaintiffs have proposed a test case approach to future discovery that we believe will help streamline the litigation, reduce the burden on the Court and the parties, and provide a guide as to the range of outcomes for the remaining drugs. Plaintiffs welcome an opportunity to discuss this should the Court believe that this discussion might benefit case management.

I. STATUS OF DISCOVERY

A. Discovery Efforts to Date

After the Court issued its order of May 13, 2003, plaintiffs served all defendants whom we believed were subject to discovery with requests for production and 30(b)(6) deposition notices.[1] Thereafter, a significant amount of time and energy was expended on the issue of which defendants and drugs were subject to discovery as a result of the May 13 Order. Initially, defendants did not formally respond to these requests. Instead those defendants that agreed to produce proposed timetables for doing so that seemed reasonable at the time. The majority of proposed dates of production fell in mid-September through October. If production had occurred on this timetable, the March 1 fact cutoff would have been attainable.[2] Plaintiffs will not burden the Court with the minutiae of production issues, but production responsiveness and timeliness has varied. For example, one defendant promised a full production in the September-October timeframe, received repeated requests for the production, and finally provided documents for the first time on January 21, 2003, less than six weeks from the fact discovery cutoff. Other defendants made their productions in November or December, well after when they had promised to produce. Plaintiffs also proceeded with third party subpoenas to the publishers, PBMs, and industry trade associations. The production of documents from these nonparties has been painstakingly slow, but plaintiffs are making progress. The fact discovery cutoff of March 1 is also made untenable by the slowness of these third party productions. Plaintiffs point this out not to cast blame, but to alert the Court that, as a result of being reasonable (perhaps too

[1] The First and Amended requests were served on June 17 and 19, 2003 and the deposition notices on June 17, 2003.

[2] Formal responses to the first discovery requests were not received until November, December, 2003 or January 2004.

reasonable), there is insufficient time to complete fact discovery given the late production of documents.

B. Post November 21 Discovery

At the November 21 hearing, the Court ordered that discovery proceed with respect to brand name Part B drugs. Plaintiffs immediately served requests for production of documents with respect to all brand name drugs for which a plaintiff had purchased the drug. Despite the clear indication that discovery was to expand, at least two defendants who manufacture brand name drugs – Amgen and Hoffman – just ignored the Court's order and refused to respond. Each filed briefs which in large measure completely regurgitate their defendant-specific motions to dismiss, which the Court had no doubt reviewed prior to issuing the November 21, 2003 Order.

Other defendants appear to now unilaterally narrow discovery. In their memorandum, defendants claim that, if discovery is limited to Medicare Part B drugs, "then issues relating to the reimbursement of Medicare Part B drugs by private payors outside of the Part B context, as well as issues relating to drugs sold through PBMs, would not be subject to discovery." Defs. Mem. at 6-7.

However, the AMCC alleges that defendants inflate the AWPs for Part B covered drugs both in the Medicare context ***and*** when third party payors reimburse for those same drugs outside of Medicare. AMCC ¶¶ 134, 141, 163, 168-78. In other words, the AMCC not only alleges that defendants' AWP scheme targets Medicare's use of AWP as a reimbursement tool, the AMCC also clearly alleges that AWP is used for reimbursement purposes when a drug that happens to be covered by Medicare Part B is used by a non-Medicare patient where the third party payor reimburses directly, or through a PBM, based on AWP. AMCC ¶ 168-78. Thus, this

new discovery limitation arbitrarily imposed by defendants is baseless and should be swiftly rejected.

II. CASE MANAGEMENT SUGGESTIONS

A. Need for Immediate Relief From the Current Phase 1 Deadlines

As noted above, with a March 1, 2004 deadline looming, plaintiffs do not believe that they can complete fact discovery by March 1, and suggest that all current dates for the original drugs that are subject to discovery be extended by 60 days.

B. Scope of Phase 2 Drugs

There are disputes as to which drugs are covered by the November 21, 2003 ruling. There is a dispute now surfacing for the first time that defendants seek to unilaterally rewrite the AMCC and limit the brand name case only to Medicare Part B reimbursement situations. As noted above, this is contrary to the allegations of the AMCC, as a few additional examples from the AMCC make perfectly clear. For example, a Glaxo memorandum cited in the complaint notes that increasing the AWP to create a better spread will impact all payors:

> (3) ***Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?*** [¶ 395(3).]

Another example is found in ¶ 400 of the AMCC:

> As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of "up-dosing" rather than efficacy of Zofran. ***Though physicians have certainly benefited financially from such tactics, it is costing 3rd party payers and patients more for medication***.

Another Glaxo document directly references the impact on insurers outside of the Medicare Part B context:

> b. Expanding further on the recommendation above, elsewhere in the same document it is stated: "Because insurers

> often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor's profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain." (GSK-MDL-ZN02-034366) (Highly Confidential). [¶ 380(b).]

Aventis also acknowledged internally that AWP is not limited to Part B reimbursement but impacts all payors:

> "AWP" is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWPs are set by manufacturers as a "suggested retail" for the products they produce. ***These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement.*** (Emphasis added.) [¶ 252.]

And finally, AstraZeneca acknowledged the implementation of the AWP scheme directly with a PBM in a context not limited to Part B:

> ZENECA WILL REIMBURSE CAREMARK[3] FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA. [¶ 236(b).]

Thus, the Court needs to promptly disabuse defendants of their unilateral limitation on the scope of discovery.

C. Suggested Test Case Approach

The Court has raised informally at several hearings the idea of using creative techniques to manage discovery and trial in a way that might help the parties evaluate the case without full-blown discovery on all 324 drugs currently targeted in the AMCC. When defendants approached plaintiffs seeking a suspension of all deadlines, plaintiffs rejected that proposal. Instead,

[3] Caremark is one of the four major PBMs.

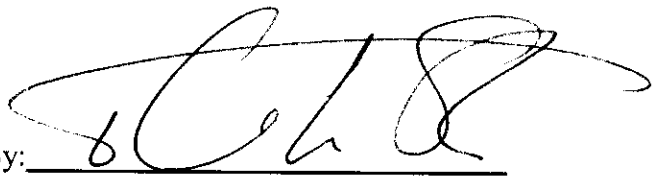
plaintiffs made two suggestions: (i) an extension of sixty days, or (ii) a new schedule using a test case approach. Under our proposal, plaintiffs would select 2 to 4 drugs from each participating defendant. Plaintiffs would select a range of types of drugs so as to cover all issues, including generic drugs, Part B and non-Part B situations, and brand name drugs that are physician administered as well as orals. The parties and Court would then set a schedule for discovery, motion practice and trial as to the selected drugs. Such test cases could provide guidance to the parties respecting resolution of claims, or streamline trial, as to the remaining drugs. This approach is recommended by the MANUAL FOR COMPLEX LITIGATION, THIRD § 33.28, which discusses innovative approaches such as "bellwether trials on all issues of a limited number of selected cases representative of the total mix, to establish a foundation for resolving the balance." *Id.* at 339. This approach would save the parties significant resources both in terms of party and nonparty discovery. Plaintiffs' propose that defendants who were not willing to agree to a test case would be subject to full-blown discovery.

Plaintiffs proposed that fact discovery on the test case drugs could be completed in nine months and that class certification could be briefed at the end of five months.

III. CONCLUSION

Plaintiffs and defendants agree that the current case management schedule should be adjusted. However, the drastic curtailment of plaintiffs' AWP-inflation claims that defendants propose is not supported by any fair reading of the AMCC or the Court's prior orders. Plaintiffs respectfully submit that their test-case proposal is cogent, reasonable and conserves scarce judicial resources and is therefore superior to defendants' suggestions.

DATED: February 4, 2004

By: 

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CERTIFICATE OF SERVICE

I hereby certify that I, Thomas M. Sobol, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Memorandum in Response to Defendants' Request for a Status Conference to be served on all counsel of record electronically on February 4, 2004, pursuant to Section D of Case Management Order No. 2.

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